510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

K003518

JAN - 9 2001

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
~~Fax (717) 854-2343~~

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: November 14, 2000

TRADE OR PROPRIETARY NAME: Rapidd™ Highspeed Dental Handpiece

CLASSIFICATION NAME: Dental Handpiece 872.4200

PREDICATE DEVICES: Midwest Tradition•PB Push Button Highspeed Handpiece K963050

DEVICE DESCRIPTION: The Rapidd™ Highspeed Dental Handpiece is an air-driven highspeed dental handpiece. Its features include: an air-driven turbine providing power and speed appropriate for use with dental carbide burs and diamond cutting instruments; fused fiber optics for illumination; all stainless steel external construction for corrosion resistance; a swivel quick-connect for connection to standard dental operatory hoses; a multi-port air-water spray for cooling of the cutting interface; a push-button chucking mechanism to grip cutting instrument with ISO standard shanks; and sealed bearings.

INTENDED USE: The Rapidd™ Highspeed Dental Handpiece is an air-powered dental handpiece for use in general dentistry.

TECHNOLOGICAL CHARACTERISTICS: The Rapidd™ Highspeed Dental Handpiece has the same basic technology, primary energy sources, maximum electrical input power, maximum input air and water pressure, maximum mechanical output energy, and base unit material as the predicate device.

The only materials in this dental handpiece which pose any potential for material release are the lubricants. All other materials of construction which come into contact with the patient are stainless steel. The lubricants were evaluated for cytotoxicity and found to be non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2001

Mr. P Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
York, Pennsylvania 17404

Re: K003518
Trade Name: Rapidd™ Highspeed Dental Handpiece
Regulatory Class: I
Product Code: EFB
Dated: November 14, 2000
Received: November 15, 2000

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known):

Device Name: Rapidd™ Highspeed Dental Handpiece

Indications for Use:

The device is an air-powered dental handpiece **for use** in general dentistry.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003518